

GUIDELINES AND REGULATIONS FOR DERMAL CORROSIVITY

AGENCY OR ORGANIZATION	GUIDELINES AND REGULATIONS ¹	COMMENTS
Consumer Product Safety Commission (CPSC)	16CFR1500 §1500.3 -Definitions §1500.4 -Human experience with hazardous substances §1500.41 -Method of testing primary irritant substances	The method involves the application of the test substance on the hair-free intact and abraded skin of at least 6 albino rabbits. http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1
Occupational Safety and Health Administration (OSHA)	29CFR1910 §1910.1200 Definition of Corrosive and Hazard Communication (includes Appendix A)	OSHA accepts determination of dermal corrosivity by Corrositex® and other <i>in vitro</i> tests. States that OSHA does not require chemical manufacturers or importers to conduct animal tests for the evaluation of the hazard potential of chemical products.
US Department of Transportation (US DOT)	Exemption allowing use of Corrositex® as an alternative test method. 49CFR 173 §173.136(a)(1) Class 8 Definitions §173.137(a), (b), (c)(1) Class 8 Assignment of Packing Group §173 Subpart J – Appendix A to part 173 – Method of Testing Corrosion to Skin 49CFR172 §172.442 Corrosive Label §172.558 Corrosive Placard	Original exemption granted 28 April 1993. Current exemption expires 31 October 2002. §173.137 requires determination of the packing group based on data from tests conducted in accordance with 1992 OECD Guideline for Testing of Chemicals, No. 404, Acute Dermal Irritation/Corrosion (OECD Draft Document, March 2000).
US Environmental Protection Agency (EPA), Office of Solid Waste and Emergency Response	62CFR32452 (13 June 1997) (final rule) affecting 40 CFR Parts 260, 264, 265, and 266. Hazardous Waste Management System; Testing and Monitoring Activities. Incorporates by reference update III of "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, 3rd ed. SW-846 Method 9040 (40CFR261.22) determines corrosivity by the pH extremes (2 or 11.5).	State-of-the-art analytical technologies for RCRA-related testing include Method 1120, Dermal Corrosion, which describes the use of the Corrositex® test kit. http://www.epa.gov/epaoswer/hazwaste/test/pdfs/1120.pdf http://www.epa.gov/epaoswer/hazwaste/test/sw846.htm

EPA, Office of Pollution Prevention and Toxic Substances (OPPTS)	OPPTS 870.2500 Acute Dermal Irritation (included as Appendix A-2)	EPA Health Effects Test Guidelines http://www.epa.gov/docs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Drafts/
EPA, Office of Pesticides	<p>40CFR152 §152.170 Criteria for restriction to use by certified applicators</p> <p>40CFR156 §156.10 Labeling requirements (skin corrosives are assigned toxicity category I)</p> <p>40CFR157 §157 Subpart B - Child-Resistant Packaging (§157.22 states requirement for pesticides corrosive to the eyes or skin)</p> <p>40CFR158 §158.690 (acute dermal toxicity testing requirement for biochemical pesticides is waived if corrosive to skin or falls within the corrosive pH ranges)</p>	
US Food and Drug Administration (US FDA)	21CFR 70 §70 Subpart C - Safety Evaluation. §70.42(b) Criteria for evaluating the safety of color additives	<p>Corrosivity not mentioned <i>per se</i>. Sensitization and primary irritation mentioned.</p> <p>No other formal regulations found with respect to corrosivity.</p>
Organization for Economic Cooperation and Development (OECD)	Harmonized integrated hazard classification system for human health and environmental effects of chemical substances.	Provides a tiered testing strategy for the evaluation of dermal corrosivity. http://www.oecd.org/ehs/Class/HC_L6.htm

¹Unless otherwise specified in the comments column, guidelines may be accessed via the US Government Printing Office (GPO) Code of Federal Regulations database <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.